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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,848	10/29/2003	Bozidar Ferek-Petric	P-10438.01	7829

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EXAMINER	
MEHTA, BHISMA	
ART UNIT	**PAPER NUMBER**
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,848	FEREK-PETRIC, BOZIDAR	
	Examiner	Art Unit	
	Bhisma Mehta	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *1-46,82 and 83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/19/2004, 03/17/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in the reply filed on December 28 2006 is acknowledged. The traversal is on the ground(s) that there is no undue burden imposed in the Examiner to examine the subject application as originally filed. This is not found persuasive because Group I and Group II are drawn to two distinct inventions and would be separately searched based on their different classification.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-45, 82, and 83 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 28 2006.

Specification

3. The disclosure is objected to because of the following informalities: Reference character 202 is used for the therapy profile in line 18 of page 10 and for the first lead in line 7 of page 11. Appropriate correction is required.

Claim Objections

4. Claims 47 and 48 are objected to because of the following informalities: There appears to be words which are missing after "46," in line 1 of claim 47. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 46, 52, 53, 56, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Weaver (U.S. Patent No. 5,389,069). Weaver discloses a method for treating a cancerous tumor comprising implanting an electroporation device (10) in a body, delivering a drug (40) to the body, and delivering at least one electrical pulse across a portion of the tumor. The drug (40) is delivered via an external drug apparatus (42). In Figure 2, Weaver shows a drug catheter (54) coupled to a housing (62) of the electroporation device. Weaver teaches programming the electroporation device which may occur after implantation (lines 23-53 of column 4).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Prutchi (U.S. Patent No. 6,152,882). Weaver discloses the method substantially as claimed. However, Weaver is silent to the step of sensing a

biological parameter and providing a sense signal based on the biological parameter. Prutchi discloses a method of electroporation with a device having a electroporating electrode and a sensing electrode (lines 11-60 of column 6) and using a temperature sensor to provide a temperature signal which is then used to control the delivery of current flow. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Weaver with a temperature sensor as taught by Prutchi as Prutchi teaches that it is well know to use temperature sensors in electroporation devices to determine the temperature of the tissue being electroporated and to use this temperature signal to control the electroporation procedure.

9. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Hofmann (U.S. Patent No. 6,120,493). Weaver discloses the method substantially as claimed. However, Weaver is silent to the step of detecting a qRs complex from an electrocardiogram and synchronizing the delivering of the electrical pulses with the qRs complex. Hofmann discloses a method for treating a cancerous tumor by electroporation and further teaches detecting a qRs complex from an electrocardiogram during the delivery of electroporation pulses (lines 19-45 of column 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the steps of detecting a qRs complex from an electrocardiogram as taught by Hofmann as Hofmann teaches that it is well known to monitor a patient's heart while the patient is undergoing the electroporation procedure.

10. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Whitehurst et al (U.S. Patent No. 6,733,485). Weaver discloses the method substantially as claimed. However, Weaver is silent to the step of measuring impedance across a portion of the tumor and comparing the impedance to a threshold impedance value. Whitehurst et al disclose a method of treating a cancerous tumor by electroporation where the impedance of the tissue being treated is measured and the delivery of the electrical pulses is adjusted based on the comparison of the impedance measured to a threshold impedance value (lines 37-49 of column 18 and lines 12-66 of column 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the step of measuring the impedance of the tumor as taught by Whitehurst et al as Whitehurst et al teach that it is well known to use a measurement of impedance across a portion of the cancerous tumor to determine if the electroporation procedure needs to be continued.

11. Claims 54, 55, 58, 59, 63-65, 67-72, and 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Sterzer (U.S. Patent No. 5,386,837). Weaver discloses the method substantially as claimed. Weaver also discloses the electroporation device as having at least one lead (20) with a therapy electrode (18) and delivering about one to about ten electrical pulses. Weaver also discloses delivering at least one electrical pulse of about 100 microseconds to about 1000 microseconds. However, Weaver is silent to the step of increasing a temperature of the body near the tumor prior to delivering an electrical pulse. Sterzer discloses a

method of treating a cancerous tumor such as a breast carcinoma by delivering a high frequency stimulus which increases the temperature at the site of the tumor (lines 45-68 of column 3), thus allowing the cells of the tumor to break down such that a chemotherapeutic drug can more easily enter the tumor. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the step of delivering a high frequency stimulus to increase the temperature near the tumor as Sterzer teaches that it is well known to increase the temperature of the tumor as it will provide for better delivery of the chemotherapeutic drug into the cells of the tumor, and thus, this will provide for better treatment of the tumor when the electrical pulses of the electroporation procedure of Weaver are applied. As to claim 59, Sterzer discloses a controlled rise of the temperature of the tumor and also allowing for a high therapeutic temperature which is below a safe temperature. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made that by increasing the temperature of the tumor by applying the high frequency stimulus as taught by Sterzer would require sensing the temperature such that the temperature of the treated tumor can be kept at a safe level. As to claim 68, Weaver discloses delivering electric pulses in the range of 100 volts to 1000 volts. Therefore, this is seen as delivering at least one electrical pulse producing an electric field strength of about 700 volts/cm to 1500 volts/cm as the actual electric field strength would be dependent on the relative location of the first and second electrode and of the size and location of the tumor being treated.

12. Claims 60 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Sterzer as applied to claims 58 and 72 above, and further in view of Hofmann. Weaver discloses the method substantially as claimed. However, Weaver is silent to the step of detecting a qRs complex from an electrocardiogram and synchronizing the delivering of the electrical pulses with the qRs complex. Hofmann discloses a method for treating a cancerous tumor by electroporation and further teaches detecting a qRs complex from an electrocardiogram during the delivery of electroporation pulses (lines 19-45 of column 17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the steps of detecting a qRs complex from an electrocardiogram as taught by Hofmann as Hofmann teaches that it is well known to monitor a patient's heart while the patient is undergoing the electroporation procedure.

13. Claims 61, 62, 66, 74, 75, and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Sterzer as applied to claims 58 and 72 above, and further in view of Whitehurst et al. Weaver discloses the method substantially as claimed. However, Weaver is silent to the step of measuring impedance across a portion of the tumor and comparing the impedance to a threshold impedance value and to the specifics of the cancerous tumor being an osteosarcoma. Whitehurst et al disclose a method of treating a cancerous tumor by electroporation where the impedance of the tissue being treated is measured and the delivery of the electrical pulses is adjusted based on the comparison of the impedance measured to a threshold impedance value (lines 37-49 of column 18 and lines 12-66 of column 19). Also, in lines

57-67 of column 8, Whitehurst et al teach treating an osteosarcoma or bone sarcoma. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Weaver with the step of measuring the impedance of the tumor as taught by Whitehurst et al as Whitehurst et al teach that it is well known to use a measurement of impedance across a portion of the cancerous tumor to determine if the electroporation procedure needs to be continued. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of Weaver to treat an osteosarcoma as taught by Whitehurst et al as both Weaver and Whitehurst et al teach using electroporation to treat cancerous tumors which can include osteosarcomas.

14. Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver in view of Sterzer as applied to claim 72 above, and further in view of Martinez (U.S. Patent No. 6,592,519). Weaver discloses the method substantially as claimed. However, Weaver is silent to detecting a drug concentration within the body. Martinez teaches an electroporation method which includes using a drug delivery catheter (110) with a sensor (130) for monitoring the amount and concentration of drug at the location in a patient's body where the drug is being delivered. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the electroporation device of Weaver with a senor for detecting the drug concentration within the body as taught by Martinez as Martinez teaches that it is well known to monitor the concentration of a drug being delivered to a patient during an electroporation procedure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

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SUPERVISORY PATENT EXAMINER